UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

NATIONAL INSTITUTES OF HEALTH, and HEALTH RESOURCES & SERVICES ADMINISTRATION

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff as for its Complaint against the above-captioned Defendants alleges as follows:

INTRODUCTION

1. Plaintiff hereby challenges a final determination of a request made to the National Institutes of Health ("**NIH**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The FOIA request at issue was for: "Any and all recommendations to the Secretary of HHS pursuant to 42 U.S.C. § 300aa-27(b)(3)." (the "**FOIA Request**"). The NIH assigned the FOIA Request Case No. 468203. The NIH forwarded the FOIA Request to the Health Resources & Services Administration, which assigned the FOIA Request Case No. 18F071.

2. In their final determination letter, the agencies failed to produce documents reflecting any recommendations that were responsive to the FOIA Request or otherwise confirm that no such documents exist. As a result, Plaintiff seeks a declaratory judgment that the Defendants' refusal to produce such documents was unlawful and an order from this Court directing Defendants to either (1) produce such documents; (2) identify an exemption allowing the Defendants to withhold such documents; or (3) state that such documents do not exist.

PARTIES

3. Plaintiff Informed Consent Action Network ("**Plaintiff**" or "**ICAN**") is a not-for-profit organization with an office located at 140 Broadway, 46th Floor, New York, New York 10005.

4. Defendant National Institutes of Health ("**NIH**") is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. The NIH is an agency within the meaning of 5 U.S.C. §552(f).

5. Defendant Health Resources & Services Administration ("**HRSA**" or collectively with NIH, "**Defendants**") is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. The HRSA is an agency within the meaning of 5 U.S.C. §552(f).

JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(a).

FACTS

I. Background

7. By 1986, the "litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines." (Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, at 2 (1994).) The remaining pharmaceutical companies producing vaccines threatened to withdraw from the vaccine market.

8. In response, Congress passed the National Childhood Vaccine Injury Act, in 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the "**1986 Act**"), which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccines. 42 U.S.C. § 300aa-11 ("No person may bring a civil action for damages in the amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death."); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) ("we hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects").

9. By granting immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces that are generally relied upon to assure the safety of all other products. Recognizing that the 1986 Act eliminated the incentive for vaccine makers to assure the safety of their vaccine products, the 1986 Act explicitly places the responsibility for vaccine safety in the hands of the United States Department of Health & Human Services ("**HHS**"). 42 U.S.C. §§ 300aa-1 through 300aa-34.

10. To that end, Section 300aa-1, entitled "Establishment," provides that "The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."

11. Section 300aa-2, entitled "Program responsibilities," provides that the National Vaccine Program's responsibilities shall include, *inter alia*:

> (1) Vaccine research. The Director of the Program shall … coordinate and provide direction for research carried out in or through the National Institutes of Health … on means to … prevent adverse reactions to vaccines.

> (2) Vaccine development. The Director of the Program shall … coordinate and provide direction for activities carried out in or through the National Institutes of Health … to develop the techniques needed to produce safe and effective vaccines.
>
> (3) Safety and efficacy testing of vaccines. The Director of the Program shall … coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health…
>
> (7) Evaluating the … adverse effects of vaccines and immunization activities. The Director of the Program shall … coordinate and provide direction to the National Institutes of Health … in monitoring … adverse effects of vaccines and immunization activities.

12. Reflecting the importance of HHS's responsibility to assure vaccine safety, Section 300aa-27(a), entitled "Mandate for safer childhood vaccines," puts this responsibility directly in the hands of the Secretary of HHS:

> (a) In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—
>
> (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
>
> (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

13. To assist the Secretary of HHS in performing these duties, Section 300aa-27(b) directs the Secretary to establish a task force responsible for making recommendations to the Secretary concerning implementation of the requirements of Section 300aa-27(a). This task force is entitled the "task force on safer childhood vaccines." (the "**Task Force**" or "**Task Force on**

Safer Childhood Vaccines"). 42 U.S.C. § 300aa-27(b). The Director of the NIH is the chair of the Task Force, which by statute also includes the Commissioner of the FDA and the Director of the CDC. *Id.*

14. As provided in Section 300aa-27(b):

> (b) Task force. . . .
>
> (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

15. The Task Force, chaired by the Director of NIH, is therefore statutorily responsible, pursuant to Section 300aa-27(b), to provide the Secretary of HHS with recommendations concerning implementation of the requirements of Section 300aa-27(a).

16. And to assure the Secretary of HHS takes action based on the recommendations made by the Task Force, Section 300aa-27(c) provides that in 1989 and "periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period."

17. The rapid growth in the number of pediatric vaccines since passage of the 1986 Act has only increased the need for the Task Force to give careful consideration to its recommendations. In 1983, the CDC's childhood vaccine schedule included 11 injections of 4 vaccines. (CDC, 1983 Childhood Immunization Schedule *available at* https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg.) As of 2018, the CDC's childhood vaccine schedule includes 56 injections of 30 different vaccines. (CDC, 2018 Childhood Immunization

Schedule *available at* https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf)

18. Plaintiff's founder, along with approximately half a dozen other individuals concerned about vaccine safety, had a two-hour meeting at the NIH in Bethesda, Maryland on May 31, 2017 with the Director of the NIH, the Principal Deputy Director of the NIH, the Counsel to the Secretary of HHS, and the Directors from various institutes at the NIH. During that two-hour meeting regarding vaccine safety with the Director of the NIH, Plaintiff became concerned that the Task Force, headed by the Director of the NIH, was not making adequate recommendations to the Secretary of HHS for improving vaccine safety as required by 42 U.S.C. § 300aa-27(b). Plaintiff therefore decided to submit a FOIA request to obtain copies of the recommendations made by the Task Force since January 1, 2009.

II. The FOIA Request

19. On August 25, 2017, Plaintiff sent the FOIA Request via email and FedEx to Susan Cornell, Freedom of Information Officer, NIH. (Exhibit A.)

20. The FOIA Request makes the following request: "Any and all recommendations to the Secretary of HHS pursuant to 42 U.S.C. § 300aa-27(b)(3)." (the "**Request**").

21. By way of background, the FOIA Request, explained as follows:

> Section 300-aa27(b) provides that "The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control." This section further provides that "The Director of the National Institutes of Health shall serve as chairman of the task force . . . [and] the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a) of this section."

(Exhibit A.)

III. Correspondence Regarding the FOIA Request

22. On August 30, 2017, Roger Bordine, FOIA Office, NIH, emailed an acknowledgment letter from the NIH assigning this request as "Case No. 46820" and stating in relevant part:

> This acknowledges your August 25, 2017, Freedom of Information Act (FOIA) request addressed to the FOIA Office, National Institutes of Health, (NIH) and received that same day. You requested a copy of any and all recommendations, by the Director of the NIH, to the Secretary of HHS pursuant to 42 U.S.C. § 300aa-27(b)(3) from January 2009 to present. You have also requested a fee waiver.
>
> We have queried the files of the appropriate NIH offices for records responsive to your request. If any responsive documents are located, they will be reviewed for releasability, and all releasable information will be sent to you.

(Exhibit B) (emphasis added.)

23. On October 24, 2017, Plaintiff's counsel followed-up with Mr. Bordine stating: "I hope this email finds you well. I am writing to you to find out the status of FOIA Case No. 46820. I appreciate your time." (Exhibit C at 5.) Mr. Bordine responded that the search was ongoing. *Id*.

24. On November 28, 2017, Plaintiff's counsel wrote to Mr. Bordine in relevant part:

> This request from August 28, 2017 is a very simple and straightforward request for recommendations (if any) made by a government task force. These should be readily accessible. Can you please explain why these recommendations, if any exist, are not readily accessible and produced? If there are no responsive documents, please just let us know.

(Exhibit C at 4.)

25. That same day, November 28, 2017, Mr. Bordine responded by stating "The search did find responsive records" and that those documents were in the queue to be reviewed. (Exhibit C at 3.) After further follow-up from Plaintiff's counsel, Mr. Bordine advised on December 21,

2017 that "The NIH FOIA Office has gathered 37 pages of records responsive to your request" but that:

> Upon initial review, we have determined that these records fall under the jurisdiction of Health Resources & Services Administration (HRSA) and as such, your request and records related to your request are being forwarded to HRSA for direct response to you. Our preliminary discussion with the HRSA FOIA Office suggest that HRSA believes these records will be ready within the next two months.

(Exhibit C at 2.)

26. Plaintiff's counsel requested that Mr. Bordine provide "the name and email address of the FOIA officer at HRSA who advised the records will be ready in the next two months." (Exhibit C at 1.) Mr. Bordine responded that he did not have this information and added that the records located by NIH "were referred to HRSA because they were created by HRSA." *Id.*

27. On December 27, 2017, Cindy Perez, FOIA Office, HRSA, sent a letter stating that her office had assigned a case number, 18F071, to the FOIA Request. (Exhibit D at 3.) Mr. Perez's email added that "The National Institutes of Health has referred approximately 37 pages to the Health Resources and Services Administration for direct response." (Exhibit D at 2.)

28. After Plaintiff's counsel twice followed-up with Mr. Perez about the status of this request, Mr. Perez stated on January 30, 2018 that "your request is with an analyst." (Exhibit D at 1.)

III. The Final Response to the FOIA Request

29. On January 31, 2018, Ms. Perez sent an email addressed to Plaintiff's Counsel stating "Your final response letter is attached." The final response letter (the "**Final Response Letter**") stated:

> This is in response to your August 25, 2017 FOIA request which you submitted to the National Institutes of Health (NIH). On

> December 21, 2017, NIH forwarded your request to this office for a direct response. In summary, you requested all recommendations created after January 1, 2009 to the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(b)(3).
>
> Upon receipt of your request, it was sent to Healthcare Systems Bureau (HSB). HSB reported that the Advisory Commission on Childhood Vaccines (ACCV) advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services on issues relating to the operation of the National Vaccine Injury Compensation Program. All ACCV reports and recommendations are available publicly, on HRSA website: https://www.hrsa.gov/advisorycommittees/childhoodvaccines/reportsrecommendations.html.

(Exhibit E at 2.)

IV. Deficiencies in the Final Response Letter

30. The Final Response Letter is deficient for several reasons.

31. First, the Final Response Letter is non-responsive to the Request. The Request sought any recommendations made by the Task Force on Safer Childhood Vaccines to the Secretary of HHS pursuant to 42 U.S.C. § 300aa-27(b)(3). (Exhibit A.) However, the Final Response Letter directs the undersigned to recommendations made by the Advisory Commission on Childhood Vaccines ("**ACCV**"). (Exhibit E.) The ACCV is a separate and independent committee, chartered under a different section of the U.S. Code, with its own statutory responsibility to make recommendations to the Secretary of HHS. 42 U.S.C. § 300aa-19. The FOIA Request sought recommendations from the Task Force, but the request cited to recommendations by the ACCV, a different advisory commission. As such, the Final Response Letter was not responsive to the FOIA Request.

32. Second, to the extent that the Final Response Letter's silence regarding any recommendations made by the Task Force indicates that no documents reflecting any such recommendation exist, we also appeal that adverse determination. 45 C.F.R. § 5.61(b) ("Adverse

determinations include: . . . Determination that a record does not exist or cannot be found"). Pursuant to 42 U.S.C. § 300aa-27(b)(3), the Task Force is required to make recommendations to the Secretary of HHS. Documentation reflecting those recommendations may only be withheld by asserting one of the exemptions listed in 45 CFR §§ 5.31, 5.32. The Final Response Letter fails to list any such exception and hence NIH must either confirm that it has no records responsive to the Request or otherwise either produce responsive records or provide a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such records.

33. Third, the NIH stated that the "NIH FOIA Office has gathered 37 pages of records responsive to your request." (Exhibit C at 2.) However, the Defendants failed to either produce these 37 pages or to assert that any exemptions listed in 45 CFR §§ 5.31, 5.32 apply to any of the 37 pages in their Final Response Letter.

IV. Administrative Appeal

34. On February 15, 2018, an administrative appeal from the final determination was filed with HHS's FOIA Office. (Exhibit F.) The appeal stated, in relevant part:

> First, the Final Response Letter is non-responsive to the Request. The Request sought any recommendations made by the Task Force on Safer Childhood Vaccines to the Secretary of HHS pursuant to 42 U.S.C. § 300aa-27(b)(3). (Exhibit A.) However, the Final Response Letter directs the undersigned to recommendations made by the Advisory Commission on Childhood Vaccines ("**ACCV**"). (Exhibit E.) The ACCV is a separate and independent committee, chartered under a different section of the U.S. Code, with its own statutory responsibility to make recommendations to the Secretary of HHS. 42 U.S.C. § 300aa-19. The FOIA Request sought recommendations from the Task Force on Safter Childhood Vaccines, but the request cited to recommendations by the ACCV, a different advisory commission. As such, the Final Response Letter was not responsive to the FOIA Request.
>
> Second, to the extent that the Final Response Letter's silence regarding any recommendations made by the Task Force indicates

> that no documents reflecting any such recommendation exist, we also appeal that adverse determination. 45 C.F.R. § 5.61(b) ("Adverse determinations include: . . . Determination that a record does not exist or cannot be found"). Pursuant to 42 U.S.C. § 300aa-27(b)(3), the Task Force is required to make recommendations to the Secretary of HHS. Documentation reflecting those recommendations may only be withheld by asserting one of the exemptions listed in 45 CFR §§ 5.31, 5.32. The Final Response Letter fails to list any such exception and hence NIH must either confirm that it has no records responsive to the Request or otherwise either produce responsive records or provide a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such records. …
>
> Given the foregoing, we request:
>
> 1. NIH to either (1) make available to Plaintiff any and all records which are responsive to the FOIA Request; (2) assert a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such records; or (3) state that no such records exist within the NIH;
>
> 2. HRSA to either (1) make available to Plaintiff any and all records which are responsive to the FOIA Request; (2) assert a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such records; or (3) state that no such records exist within the HRSA

(Exhibit F.)

35. On February 16, 2018, HHS acknowledged receipt of the administrative appeal from the Final Response Letter. (Exhibit G.) On February 28, 2018, HHS provided its final response from the administrative appeal (the "**Final Appeal Response Letter**") which stated, in relevant part:

> Upon receipt of your appeal letter dated February 15, 2018, our office realized that we inadvertently withheld the records sent to our office on December 21, 2017, by the National Institutes of Health (NIH) as a referral to your August 25, 2017, FOIA request, for recommendations created after January 1, 2009 to the Secretary of HHS pursuant to 42 U.S.C. § 300aa-27(b)(3).
>
> Please note that NIH did send our office 37 pages, however 7 of those pages included internal referral documents, which were:

> NIH's Referral for a Direct Response to HRSA (one page); NIH's Referral Memo addressed to Tom Flavin (one page); Mr. Pauley's email submitting Mr. Siri's FOIA request to NIH (three pages); and NIH's final response to Mr. Siri's FOIA request (two pages). Therefore, there are only 30 pages of responsive records. Those 30 pages are now being released to you in their entirety.
>
> Additionally, we located the Task Force on Safer Childhood Vaccines Final Report and Recommendations published by NIH/NIAID on the website at the following link, https://permanent.access.gpo.gov/lps22576/safevacc.pdf.
>
> We hope this subsequent response satisfies your appeal with HRSA.

(Exhibit H.)

36. The Final Appeal Response Letter did not cure the deficiencies identified in Plaintiff's appeal of the Final Response Letter.

37. First, the Final Appeal Response Letter is again non-responsive to the Request. The Request sought any recommendations made by the Task Force on Safer Childhood Vaccines to the Secretary of HHS pursuant to 42 U.S.C. § 300aa-27(b)(3). (Exhibit A.) However, the Final Appeal Response Letter included thirty pages of recommendations made by the Advisory Commission on Childhood Vaccines ("ACCV") pursuant to 42 U.S.C. § 300aa-19. (Exhibit H.) The ACCV is a separate and independent committee, chartered under a different section of the U.S. Code, with its own statutory responsibility to make recommendations to the Secretary of HHS. 42 U.S.C. § 300aa-19. Indeed, the thirty pages of recommendations produced typically begin by making clear, in one form or another, that they are being made "In accordance with the provisions of the charter for the Advisory Commission on Childhood Vaccine (ACCV or Commission) and pursuant to its obligations under § 300aa-19 of the National Childhood Vaccine Injury Act of 1986." (Exhibit H at 23.)

38. The Final Appeal Response Letter does provide a link to a report by the Task Force on Safer Childhood Vaccines but this report is from January 1998 and thus again non-responsive to the request which sought recommendations made by the Task Force on or after January 1, 2009.

39. Second, the Final Appeal Response Letter failed to clarify whether the Final Response Letter's silence regarding any recommendations made by the Task Force on or after January 1, 2009 indicates that no documents reflecting any such recommendation exist. 45 C.F.R. § 5.61(b) ("Adverse determinations include: . . . Determination that a record does not exist or cannot be found"). Pursuant to 42 U.S.C. § 300aa-27(b)(3), the Task Force is required to make recommendations to the Secretary of HHS. Documentation reflecting those recommendations may only be withheld by asserting one of the exemptions listed in 45 CFR §§ 5.31, 5.32. The Final Response Letter fails to list any such exception and hence NIH must either confirm that it has no records responsive to the Request or otherwise either produce responsive records or provide a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such records.

40. Third, the NIH stated that it is withholding 7 pages which it refers to as "internal referral documents." Five of these seven pages are described by HHS as "Mr. Pauley's email submitting Mr. Siri's FOIA request to NIH (three pages); and NIH's final response to Mr. Siri's FOIA request (two pages)." (Exhibit H.) The Final Appeal Response Letter fails to assert a statutory basis for withholding these documents -- which comprise communications with Plaintiff's counsel -- and hence they should be produced. As for the remaining two pages being withheld, these are described by HHS as "NIH's Referral for a Direct Response to HRSA (one page); NIH's Referral Memo addressed to Tom Flavin (one page)." (Exhibit H.) Again, the Final Appeal Response Letter fails to assert a statutory basis for withholding these documents and these two pages should also be produced.

Requested Relief

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an Order declaring that it was unlawful for the Defendants to fail to either (1) disclose the recommendations made after January 1, 2009 by the Task Force for Safer Childhood Vaccines pursuant to 42 U.S.C. § 300aa-27(b), (2) assert an exemption for such documents, or (3) state that no such documents exist;

c. Enter an Order directing the NIH to either (1) make available to Plaintiff any and all records which are responsive to the FOIA Request; (2) assert a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such records; or (3) state that no such records exist within the NIH;

d. Enter an Order directing the HRSA to either (1) make available to Plaintiff any and all records which are responsive to the FOIA Request; (2) assert a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such records; or (3) state that no such records exist within the HRSA;

e. Enter an Order directing Defendants to produce the seven pages of documents identified in their letter of February 28, 2018;

f. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

g. Grant such other relief as the Court may deem just and proper.

Dated: March 6, 2018

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